MAINTENANCE LEVEL 2

M2-MS Hepatitis C Treatment Adjustment

RECOMMENDATION SUMMARY TEXT

The Health Care Authority (HCA) requests a reduction of $44,418,000 ($10,789,000 GF-State) in the 2016 Supplemental due to lower-than-anticipated treatment costs for the hepatitis C virus (HCV). The HCA originally projected that HCV treatment would be provided to approximately 3,600 Medicaid HCV patients by June 2015. Treatment has been provided to approximately 1,200 Medicaid HCV patients to date.

PACKAGE DESCRIPTION

Hepatitis C is a chronic viral infection of the liver that affects approximately 1 percent of the U.S. population, or over three million people. In Washington State, estimates are that 75,000 to 100,000 people are infected with hepatitis C. If untreated, about 35 percent of patients infected will develop chronic liver disease, cirrhosis, or liver cancer over a time span of 20 to 30 years.

Liver scarring (i.e. fibrosis) caused by hepatitis C is categorized along a continuum, from absent (F0) to severe (F4, which equates to cirrhosis). The more severe a person's fibrosis, the more likely they are to develop complications, and possibly die of their disease.

Advances in the treatment of hepatitis C have led to the availability of highly effective and safe medications that are administered orally either once or twice daily. These medications are cost-effective at a population level as measured by the cost per quality adjusted life year gained. Although the high prevalence of infection and the cost of treating a single individual (the Average Wholesale Price for a treatment course is approximately $85,000 to $95,000) initially made treating all patients with chronic hepatitis C infection cost prohibitive, additional medications to treat hepatitis C have been approved by the federal Food and Drug Administration (FDA) resulting in price competition in the market place. Albeit still expensive, these treatments are now much more affordable.

In 2015, based on estimates of the prevalence of hepatitis C infection in the Medicaid population; the proportion of persons thought to have F3-F4 disease; and the rate at which patients would come into care, the HCA requested, and the legislature appropriated, funding for hepatitis C treatment. Analyses of available data suggest that persons with hepatitis C are not coming into care as rapidly as was anticipated; in addition, it is possible that the prevalence of F3-F4 disease in the Medicaid population is less than estimated. Finally, supplemental rebates for the preferred hepatitis C treatments, which were finalized after the development and implementation of the HCA's clinical policy, provide the state with a considerable discount for the preferred medications, Harvoni and Sovaldi.

Analyses suggest persons with HCV are not coming into care as rapidly as anticipated; or, it is possible the prevalence of severe liver disease in the Medicaid population was over estimated in the original model. The Medicaid HCV coverage policy was created to ensure patients with HCV who are at the

highest risk for liver-related complications received treatment first, therefore the policy limits treatment to those with severe liver disease.

The initial policy estimated the number of Medicaid persons infected with the hepatitis C virus; the prevalence of severe liver disease in this population; and the rate at which persons would be identified, staged and treated. Actual experience indicates that persons with hepatitis C are being identified and entering into treatment at a rate slower than initially anticipated. In addition, the cost of the newer more effective hepatitis C medications, while still extraordinarily expensive, is less than initially modeled.

Kate LaBelle, Financial Services: 360-725-1846 or kate.labelle@hca.wa.gov
Daniel Lessler, MD, Chief Medical Officer: 360-725-1612 or daniel.lessler@hca.wa.gov

FISCAL DETAILS/OBJECTS OF EXPENDITURE

	FY 2016	FY 2017	Total
1. Operating Expenditures:			
Fund 001-1 GF-State	$ (18,859,000)	$ 8,070,000	$ (10,789,000)
Fund 001-C GF-Federal Medicaid Title XIX	$ (56,425,000)	$ 22,796,000	$ (33,629,000)
Total	**$ (75,284,000)**	**$ 30,866,000**	**$ (44,418,000)**

	FY 2016	FY 2017	Total
2. Staffing:			
Total FTEs	-	-	-

	FY 2016	FY 2017	Total
3. Objects of Expenditure:			
A - Salaries And Wages	$ -	$ -	$ -
B - Employee Benefits	$ -	$ -	$ -
C - Personal Service Contracts	$ -	$ -	$ -
E - Goods And Services	$ -	$ -	$ -
G - Travel	$ -	$ -	$ -
J - Capital Outlays	$ -	$ -	$ -
N - Grants, Benefits & Client Services	$ (75,284,000)	$ 30,866,000	$ (44,418,000)
Other (specify) -	$ -	$ -	$ -
Total	**$ (75,284,000)**	**$ 30,866,000**	**$ (44,418,000)**

	FY 2016	FY 2017	Total
4. Revenue:			
Fund 001-C GF-Federal Medicaid Title XIX	$ (56,425,000)	$ 22,796,000	$ (33,629,000)
Total	**$ (56,425,000)**	**$ 22,796,000**	**$ (33,629,000)**

NARRATIVE JUSTIFICATION

WHAT SPECIFIC PERFORMANCE OUTCOMES DOES THE AGENCY EXPECT?

Over the course of the biennium, it is estimated that approximately 2,700 clients with chronic hepatitis C will undergo treatment. Based on available research data, estimates are that up to 90 percent of clients could have a sustained viral response (SVR) to treatment. Those with an SVR would be far less likely to progress to advanced liver disease (i.e. cirrhosis or liver cancer) or experience other complications associated with chronic hepatitis C infection, including death.

PERFORMANCE MEASURE DETAIL

Activity Inventory

H005 HCA National Health Reform
H011 HCA All Other Clients – Fee for Service – Mandatory Services

IS THIS DECISION PACKAGE ESSENTIAL TO IMPLEMENT A STRATEGY IDENTIFIED IN THE AGENCY'S STRATEGIC PLAN?

Yes. The HCA's strategic plan emphasizes the triple aim: better population health, more effective care, and lower costs. Effective treatment of hepatitis C will improve population health.

DOES THIS DECISION PACKAGE PROVIDE ESSENTIAL SUPPORT TO ONE OR MORE OF THE GOVERNOR'S RESULTS WASHINGTON PRIORITIES?

Yes. This strategy supports Goal 4.1.2: Decrease the proportion of adults reporting fair or poor health. Patients with chronic hepatitis C who develop cirrhosis and its complications are likely to report overall poor health status. By treating chronic hepatitis C, patients will avoid adverse health consequences, and be more likely to report better health status.

WHAT ARE THE OTHER IMPORTANT CONNECTIONS OR IMPACTS RELATED TO THIS PROPOSAL?

Since hepatitis C is undiagnosed in 25 to 50 percent of those persons affected, and because it can often result in chronic disease, there is a large public health push to identify persons with infection. This is a message shared by the federal Centers for Disease Control (CDC), local health departments, and hepatitis advocacy groups. In addition, because the new therapies are so effective, there is the potential to completely eradicate the disease. As such, all of the aforementioned groups are advocating for the treatment of all patients with hepatitis C. The medical community, in particular providers caring for patients with hepatitis C, are also advocating for the treatment of their patients who have progressed with their disease now that better tolerated and more effective drugs are available.

From a legal standpoint, state Medicaid programs are required to cover FDA approved drugs for which the manufacturer has negotiated a federal rebate. Such is the case for Sovaldi. However, Washington State Medicaid can impose reasonable medical necessity criteria in making coverage determinations.

WHAT ALTERNATIVES WERE EXPLORED BY THE AGENCY, AND WHY WAS THIS ALTERNATIVE CHOSEN?

The only viable alternative to this strategy is to treat people with more severe disease: those patients who by definition have cirrhosis, liver cancer or are in need of a liver transplant. Not only would this be extremely unpopular among all stakeholder groups and a short-sided risk management strategy, it would be objectionable from a medical ethical standpoint.

WHAT ARE THE CONSEQUENCES OF NOT ADOPTING THIS PACKAGE?

Adoption of this request would allow for treatment of those patients most at risk for progression of their chronic liver disease, with an overall improvement in individual clinical outcomes and population health. The stakeholders mentioned above – public health, advocacy groups and the provider community – will voice concern that there are any restrictions placed on treatment, but they will be more supportive of this option than waiting until more advanced disease has occurred.

WHAT IS THE RELATIONSHIP, IF ANY, TO THE STATE CAPITAL BUDGET?

None

WHAT CHANGES WOULD BE REQUIRED TO EXISTING STATUTES, RULES, OR CONTRACTS TO IMPLEMENT THE CHANGE?

None

EXPENDITURE AND REVENUE CALCULATIONS AND ASSUMPTIONS

REVENUE CALCULATIONS AND ASSUMPTIONS:

The original 2015-2017 biennium budget included a funding step for Hepatitis C treatments. The federal revenue impact calculation is the difference between current federal funding and the Hepatitis C federal funding included in the Fall 2015 forecast. See the backup document.

EXPENDITURE CALCULATIONS AND ASSUMPTIONS:

The original 2015-2017 biennium budget included a funding step for Hepatitis C treatments. The expenditure impact calculation is the difference between current funding and the Hepatitis C funding included in the Fall 2015 forecast. See the backup document.

DISTINCTION BETWEEN ONE-TIME AND ONGOING COSTS:

Costs are expected to be ongoing.

BUDGET IMPACTS IN FUTURE BIENNIA:

Hepatitis C treatment will continue to be offered into future biennia.